

**REMARKS**

Claims 1-24 are currently pending in the application. By this amendment, claims 1, 5, 13 and 19 are amended and claims 20-24 are added for the Examiner's consideration. The specification is amended to correct minor errors. The drawings are also amended to comply with the Examiner's request. Support for the amendment(s) and added claims 20-24 is provided in at least Figure 4 and at page(s) 7-9 of the present specification. No new matter is added. Reconsideration of the rejected claims in view of the above amendments and the following remarks is respectfully requested.

***Objection to Drawings***

The drawings were objected to due to lack of descriptive legends in the hollow rectangular boxes in Figures 4 and 5. Also, the Examiner indicates that Figures 1, 2 and 8 should be labeled individually.

Applicants have revised Figures 4 and 5 to include legends in the rectangular boxes. Applicants have also revised Figure 4 to change the reference numeral of the second conduit from "26" to "31". Reference numeral 26 now only represents the control unit of Figure 4.

As to the labeling of the Figures 1, 2 and 8, Applicants note that each of these Figures appear to be appropriately numbered and described adequately in the specification. For example, at pages 6 and 7 of the specification, the figures are adequately described. If there is anything further required, the Examiner is respectfully requested to provide such indication in the next office action.

***Priority Claim***

The Examiner is of the opinion that the non-provisional application is non-enabling for this application and that the claim of priority is deficient.

Applicants first submit that the Examiner has the burden of showing that the priority document is non-enabling. According to MPEP 2164.04,

As stated by the court, "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." 439 F.2d at 224, 169 USPQ at 370.

While the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection. [But,] in accordance with the principles of compact prosecution, if an enablement rejection is appropriate, the first Office action on the merits should present the best case with all the relevant reasons, issues, and evidence so that all such rejections can be withdrawn if applicant provides appropriate convincing arguments and/or evidence in rebuttal.

However, Applicants submit that the Examiner has not met this burden. It is respectfully submitted that the Examiner has merely made a conclusion without providing adequate evidence or reasoning which is inconsistent with any statements within the priority document to rebut the presumption of enablement. For this reason, Applicants submit that the Examiner has not met his burden under MPEP §2164 and this objection should now be withdrawn.

In any event, Applicants submit that the provisional application provides ample support for the application and is enabling for many aspects in accordance with MPEP §2165(a). For example, the priority document discloses at page 1:

Main drive components of the mechanical lung include a computer controlled linear actuator. A computer is equipped with a waveform generation program that allows users to create a realistic respiration pattern that is outputted to the actuator. The actuator, in turn, acts as a diaphragm and moves air in and out of lung reservoirs.

The claims of the provisional application also provide support for enablement. For example, claim 1 recites the use of an actuator and a wave-form generator. Additionally, claim 3 recites the use of an oral and nasal passageway. This similar claim language is also found in the present application.

By the disclosure of the priority document and the state of the art, specifically as shown in U.S. 5,584,701, as applied by the Examiner to the claimed invention, it is Applicants reasoned opinion that, as filed, the provisional application would have allowed one of ordinary art to practice the invention without undue experimentation. For example, the critical aspects of a wave-form generation device to simulate breathing as well as the two passageways were disclosed in the priority document, and would allow one of ordinary skill in the art to practice the invention.

For this reason, Applicants submit that the priority document is enabling and the filing date of the priority document should be accorded to the present application.

### ***Specification***

The specification has been amended in order to correct minor inconsistencies. For example, the second conduit and the control unit were both labeled “26”. To correct this oversight, the second conduit is now labeled “31”.

### ***35 U.S.C. §112 Rejection***

Claim 19 was rejected under 35 U.S.C. §112, 2<sup>nd</sup> paragraph. This rejection is respectfully traversed.

Claim 19 has been amended to depend from claim 18. The claim terms of claim 19 now have proper antecedent support.

Accordingly, Applicants respectfully request that the rejection over claim 12 be withdrawn.

***35 U.S.C. §102 Rejection***

Claims 1-11 and 13-18 were rejected under 35 U.S.C. §102(b) for being anticipated by U.S. Patent No. 5,584,701 to Lampotang. This rejection is respectfully traversed.

The present invention is directed to a mechanical lung to provide simulated responses of breathing patterns. In one implementation, the mechanical lung can represent the breathing pattern through a nasal passage, an oral passage or both the nasal passage and the oral passage. This can be accomplished by having two passageways in fluid communication with the outlet of a reservoir, e.g., a lung. By having both the nasal and oral passageway, a more accurate simulation of breathing can be provided by the invention. For example, the invention can accurately assess and control movement of fluid in and out of the reservoir through an outlet leading to two passageways based on the waveform and respiratory pattern of a nasal, oral or nasal and oral breathing. In this manner, the suffocation risk of a child, for example, under different occlusions may be assessed such as when there is a blockage that causes complete or partial occlusion in the nasal or oral passageway.

However, the Lampotang reference does not show the features of the claimed invention. Referring to Figure 2 of Lampotang and the accompanying text at cols. 16-19, it is shown that the mechanical lung only includes a single passageway 105 having a controllable bronchial resistance 124 (e.g., a valve) (col. 17, lines 58-65). In operation, Lampotang cannot simulate either or both a nasal and/or oral passageway blockage. This does not even appear to be contemplated by Lampotang, which, instead, is more directed to the measurement of different gases within the lung, not necessarily different blockage scenarios in the nasal or oral passageways.

Additionally, Applicants submit that Lampotang also does not show a pair of cylinders connected in parallel by a conduit (claim 2) or an actuator that includes a piston disposed in the reservoir. The piston of the invention is designed to provide pressure within the reservoir. Instead, and referring again to Figure 2, Lampotang shows a bellows 100, which is in communication with the outlet. The bellows is not a pair of cylinders. The only disclosure of a

cylinder and piston assembly is shown as reference numeral 112, which is designed to actuate the bellows.

Also, Lampotang does not show a pressure transducer in fluid communication with the reservoir and electrically coupled to the control unit to measure a pressure (claims 10, 11 and 18). The Examiner notes that col. 17, lines 48-52 shows a pressure transducer. However, this passage refers to a pressure sensor 101 which is used to constantly assay the gas pressure. Here, assay refers to an analysis to determine the presence, absence, or quantity of one or more components within the gas. This sensor, however, is not designed to measure the gas pressure, itself. Instead, to measure pressure, Lampotang shows an excursion sensor 118 which is a rack 116 and pinion system which is mechanically coupled to a shaft encoder and the bellows. But, the excursion sensor 118 is not a pressure transducer in fluid communication with the reservoir.

Accordingly, Applicants respectfully request that the rejection over claims 1-11 and 13-18 be withdrawn.

***35 U.S.C. §103 Rejection***

Claims 12 and 19 were rejected under 35 U.S.C. §103(a) for being unpatentable over Lampotang in view of U. S. Patent No. 5,975,748 to East, IV. This rejection is respectfully traversed.

Claims 12 and 19 are dependent from distinguishable base claims 1 and 13, respectively. The East, IV reference does not compensate for the deficiencies of the Lampotang reference as discussed above. Thus, for the reasons set forth above, claims 12 and 19 are also distinguishable claims and are in condition for allowance.

Accordingly, Applicants respectfully request that the rejection over claims 12 and 19 be withdrawn.

***New Claims***

Claims 20-24 are added for the Examiner's consideration. Claims 20-24 contain allowable subject matter which is not shown in the applied references. For example, the applied references do not show two different valves, nor do these references show two passageways representing the oropharynx and nasopharynx, or other features of these claims.

**CONCLUSION**

In view of the foregoing amendments and remarks, Applicants submit that all of the claims are patentably distinct from the prior art of record and are in condition for allowance. The Examiner is respectfully requested to pass the above application to issue. The Examiner is invited to contact the undersigned at the telephone number listed below, if needed. Applicants hereby make a written conditional petition for extension of time, if required. Please charge any deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 23-1951.

Respectfully submitted,



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